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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,178	07/17/2000	Stacey Efstathiou	5673-55696	8385

7590 03/18/2003

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/617,178	Applicant(s) EFSTATHIOU ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-20 and 22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-20 and 22-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

2. Claims 17-20 and 22-39 are under consideration in the instant application.

3. This Office Action will be in response to applicant's arguments, filed 1/8/03 (Paper No. 19). The rejections of record can be found in the previous Office Action (Paper No. 17).

Drawings

4. The drawings filed 1/8/03 have been found acceptable by the Draftsman.

Foreign Priority

5. It is again acknowledged that foreign priority document GB9916703, filed 8/24/01, appears to provide adequate written support for the instant claims 17-20, 22-27 and 29-39.

Applicant in the Response filed 1/8/03 directs the Examiner to page 8, paragraph 3 of GB9916703 for support for the limitation "coupled protein". Applicant has previously pointed to page 2, lines 33-34 of GB9916703 for support for the limitation "coupled protein".

While the two locations pointed to in GB9916703 for support for the limitation "coupled protein" do provide two species in which the M3 protein is in fact a "coupled protein"; Applicant is attempting to rely upon two species to provide adequate written support for a generic limitation that was not clearly disclosed in foreign priority document GB9916703. In the absence of some support for the generic concept, these two species do not appear to be support for the broader genus of the "coupled protein" recited in instant claim 28.

Claim Objections

6. Claims 24-26 and 28 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. It is noted that in each of claims 24-26 and 28, the addition of a label or a coupled protein broadens, rather than limits the subject matter of claim 17.

Applicant's argument, filed 5/1/02 and reiterated 1/8/03, that the breadth of the terms "M3 protein" and "chemokine" encompass both unlabeled and labeled forms has again been fully considered but has not been found convincing.

As previously noted, the specification does not appear to support Applicant's assertion that the terms "M3 protein" and chemokine encompass labeled forms of these molecules as no definition specifically encompassing these modified forms could be identified by the Examiner. It is noted that MHV68 does not produce the M3 protein in labeled form; neither are chemokines or chemokine receptors produced by cells in labeled form.

Thus in the absence of a definition in the specification indicating that both labeled and unlabeled forms are encompassed by a given term, the addition of a label broadens rather than limits the subject matter of the previous claim.

Claim Rejections - 35 USC § 112 first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 17-20 and 22-39 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising contacting cells with the M3 protein of MHV68, does not reasonably provide enablement for the full breadth of an "M3 protein or functional homologue thereof". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments, filed 1/8/03, have been fully considered but have not been found convincing, essentially for the reasons of record set forth in Paper No. 17.

The full rejection of record may be found in Paper No. 17.

Applicant again submits that homologs of the M3 protein of MHV68 can be readily identified by one of skill in the art using the guidance provided in the specification with respect to binding assays which permit the skilled artisan to identify a homolog of M3 that binds a chemokine of interest. Applicant further points out that the specification discloses that functional homologues of M3 include fusion proteins, derivative and fragments of M3 (pages 6-7 and 18-19). Applicant argues that van Berkel et al. (J. Virol. 2000; 74: 6741-6747, of record) also discuss MHV68 homologues at page 6746, last paragraph. Finally, Applicant again submits that the specification provides sufficient guidance as to how to make M3 homologues, including guidance regarding the identity of derivatives that have certain amino acid motifs changed or deleted (e.g., page 5 at lines 1-8), and that the specification provides guidance in the bridging paragraph of pages 1 and 2 as to how to obtain M3 homologues.

Regarding the screening assay, the Examiner maintains that guidance with respect to how to identify a homologue, once made, does not provide guidance as to how the skilled artisan should alter the M3 protein of MHV68 to make functional homologues thereof.

Further, it is again noted that "functional homologue" encompasses a plethora of proteins because the specification discloses in the bridging paragraph of pages 1-2 that proteins having at least about 20% homology to M3 are encompassed by the term.

It is once again noted that the specification does not appear to have established a structural basis for the ability of the M3 protein to bind chemokines. The Examiner again points out that van Berkel et al. (J. Virol. 2000; 74: 6741-6747, of record) teach that the chemokine binding function of various viral proteins likely arose by convergent evolution, because proteins with this function are apparently *unrelated at the primary amino acid sequence level* (see especially page 6746, 3rd paragraph).

Thus *in the absence of some recognized structural basis for the function of chemokine binding*, it would require undue experimentation of the skilled artisan to select other proteins having at least 20% homology that could then be screened for the desired function of binding a chemokine. Applicant has not provided the skilled artisan with sufficient guidance as to the identity of residues to be changed, to be left unchanged, or to be deleted. The disclosure with respect to the reduction in antigenicity (specification at page 5, lines 1-8) is noted; however this does not appear to provide any particular guidance with respect to which amino acids of M3 should or should not be modified.

Without clear direction and guidance as to the nature of the changes to be made to the reference M3 protein of MHV68; the skilled artisan would be faced with undue experimentation to produce the large number of proteins encompassed by a "functional homologue" and determine if there were any operative embodiments that would result in the recited functional activity of binding a chemokine and blocking the binding of the chemokine to its receptor.

The derivations of M3 required to produce a "functional homologue" are not simply alterations in functional groups associated with a core chemical structure; instead they encompass extensive changes in an amino acid sequence for which there does not appear to be sufficient guidance regarding how the structure of M3 provides its function of binding chemokines.

Finally, it is noted that the "homologs" discussed by van Berkel et al. and pointed to by Applicant are not based upon the M3 sequence, but instead refer to the cellular proteins whose function M3 and other viral proteins mimic. Since the specification appears to limit the usage of the term "functional homologue" of M3 to other proteins with at least the 20% amino acid sequence homology over the entire sequence (bridging paragraph of pages 1-2), the comment by van Berkel et al. of "homologs" of M3 does not appear to be relevant to the instant claims.

Thus the Examiner continues to maintain for the reasons of record that the specification does not appear to provide the skilled artisan with sufficient guidance to make and use a "functional homologue" of the M3 protein of MHV68 commensurate in scope with the claimed invention, particularly in view of the single working example (the M3 protein itself) and the myriad structures encompassed by the term "functional homologue".

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The changes which can be made in the structure of the M3 protein of MHV68 and still provide or maintain the activity of binding a chemokine are unpredictable in view of the limited guidance provided in the specification. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The rejection is maintained for the reasons of record.

Conclusion

9. No claim is allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
March 17, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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3/17/03